

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH CAROLINA
CHARLESTON DIVISION

In re Bausch & Lomb Inc. Contacts Lens)	
Solution Products Liability Litigation)	
)	MDL No. 1785
)	
<i>This order relates to:</i>)	C/A No. 2:06-MN-77777-DCN
)	
Non- <i>Fusarium</i> keratitis)	
personal injury cases ¹)	ORDER & OPINION
)	
_____)	

This matter is currently before the court on defendant's motion for summary judgment on all claims and causes of action asserted by non-*Fusarium* plaintiffs.² With the exclusion of plaintiffs' causation expert regarding eye infections other than *Fusarium* keratitis, it has become clear that the remaining plaintiffs have no admissible evidence to support their allegation that defendant's Renu with MoistureLoc ("MoistureLoc") contact lens solution caused the eye infections they experienced. Consequently, these plaintiffs cannot prove an essential element in each of their cases. Therefore, and for the reasons set forth below, the court grants defendant's motion in part. However, as explained in the order, the following cases will remain under advisement: 07-1568 (Deliz-Velez), 06-3278 (Erickson), 06-3272 (Declet-Flores), 06-3273 (Garcia), and 06-3640 (Shallcross).

I. BACKGROUND

Each plaintiff whose personal injury case was consolidated to this MDL

¹ Specifically, this order applies to those cases listed in the attachment.

² Some non-*Fusarium* plaintiffs have sued entities other than defendant Bausch & Lomb. Defendant Bausch & Lomb now moves for summary judgment on behalf of all defendants.

proceeding was required to submit a Plaintiff Fact Sheet, along with medical documentation demonstrating his or her use of MoistureLoc and the type of eye infection he or she allegedly experienced as a result of using MoistureLoc. As of the date of defendant's summary judgment motion, 348 plaintiffs had not submitted any documentation showing that they experienced a *Fusarium* keratitis infection. This order concerns these "non-*Fusarium* plaintiffs," who are residents of forty-two different states plus the territory of Puerto Rico.

The court established a schedule for the identification and deposition of expert witnesses. When the parties completed expert depositions in April 2009, Dr. Elisabeth Cohen was plaintiffs' sole general causation expert with respect to non-*Fusarium* infections. In May 2009, defendant moved to exclude Dr. Cohen's expert testimony pursuant to Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 592 (1993). After a joint hearing with the Supreme Court of the State of New York, the court granted defendant's motion in August 2009, excluding Dr. Cohen's general causation opinions relating to non-*Fusarium* infections.

II. DISCUSSION

A. Summary Judgment Standard

Summary judgment is appropriate when, after considering the full evidentiary record, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). When the party moving for summary judgment does not bear the ultimate burden of persuasion at trial, the burden for summary judgment may be discharged by pointing out to the court that there is an absence of

evidence to support the nonmoving party's case. Celotex Corp. v. Catrett, 477 U.S. 317, 325 (1986). The non-movant must then "make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Id. at 322. Evidence should be viewed in the light most favorable to the nonmoving party and all inferences drawn in its favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). However, a mere "scintilla" of evidence will not preclude summary judgment. Id. at 252.

B. General Causation

"Where a medical causal relation issue is not one within the common knowledge of the layman, proximate cause cannot be determined without expert medical testimony." Goewey v. United States, 886 F. Supp. 1268, 1279 (D.S.C. 1995) (citation omitted). To establish medical causation in a product liability case, a plaintiff must show both general causation and specific causation. See Golden v. CH2M Hill Hanford Group, Inc., 528 F.3d 681, 683 (9th Cir. 2008) (noting that, to survive summary judgment, plaintiff must show that he was exposed to chemicals that could have caused the physical injuries he complains about (general causation), and that his exposure did in fact result in those injuries (specific causation)).

"General causation is whether a substance is capable of causing a particular injury or condition in the general population, while specific causation is whether a substance caused a particular individual's injury." Knight v. Kirby Inland Marine Inc., 482 F.3d 347, 351 (5th Cir. 2007) (citation omitted). "Evidence concerning specific causation in toxic tort cases is admissible only as a follow-up to admissible general-causation

evidence.” Id. (citing Raynor v. Merrell Pharm., 104 F.3d 1371, 1376 (D.C. Cir. 1997)).

As the Fifth Circuit explained,

Thus, there is a two-step process in examining the admissibility of causation evidence in toxic tort cases. First, the district court must determine whether there is general causation. Second, if it concludes that there is admissible general-causation evidence, the district court must determine whether there is admissible specific-causation evidence.

Id. (citation omitted); see Norris v. Baxter Healthcare Corp., 397 F.3d 878, 881 (10th Cir. 2005) (“Plaintiff must first demonstrate general causation because without general causation, there can be no specific causation.”). “If a plaintiff is not able to establish general causation, it is unnecessary to consider whether the plaintiff can establish specific causation.” Dunn v. Sandoz Pharms. Corp., 275 F. Supp. 2d 672, 676 (M.D.N.C. 2003) (citing Raynor, 104 F.3d at 1376); see Mack v. AmerisourceBergen Drug Corp., --- F. Supp. 2d ----, 2009 WL 3209032, at *2 (D. Md. 2009) (noting that proof of general causation is a prerequisite to proving specific causation).

Based on this well-established rule requiring proof of general causation, the non-*Fusarium* plaintiffs’ claims cannot survive. Dr. Cohen, plaintiffs’ only general causation expert, has been excluded. Defendants have provided, and the court has reviewed, summaries of the law on this issue in all the applicable jurisdictions. Based on these summaries and the court’s own research, it appears that the concept of general causation as a necessary precursor to proving specific causation is the rule in all jurisdictions. See Mary Sue Henifin, Howard M. Kipen & Susan R. Poulter, Reference Guide on Medical Testimony, in REFERENCE MANUAL ON SCIENTIFIC EVIDENCE 439, 444 (Fed. Jud. Ctr., 2d ed. 2000). Consequently, plaintiffs’ claims cannot survive given the court’s Daubert

ruling excluding Dr. Cohen's testimony.

Plaintiffs respond that, as their previously filed motion for partial summary judgment shows, MoistureLoc is defective.³ This, however, is irrelevant. Plaintiffs must prove defect *and* causation. See Hunter v. Philip Morris USA, 582 F.3d 1039, 1045 (9th Cir. 2009); Little v. Brown & Williamson Tobacco Corp., 243 F. Supp. 2d 480, 489 (D.S.C. 2001). A complete failure of proof on either element is a fatal blow to plaintiffs' claims. Without Dr. Cohen's testimony, plaintiffs simply cannot prove general causation.

Plaintiffs also argue that, the exclusion of their general causation expert notwithstanding, individual plaintiffs may be able to prove causation through physicians' differential diagnoses. "A differential diagnosis, which courts have recognized as a reliable methodology when conducted properly, 'is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated.'" Foster v. Legal Sea Foods, Inc., 2008 WL 2945561, at *10 (D. Md. 2008) (quoting Westberry v. Gislaved Gummi AB, 178 F.3d 257, 262 (4th Cir. 1999)). "To be reliable, a differential diagnosis must first 'rule in' a plaintiff's proposed cause and then 'rule out' alternative causes." Id. (citing Westberry, 178 F.3d at 263). "Ruling in' a cause, also known as proving 'general causation', 'is established by demonstrating that exposure to a substance can cause a particular disease.'" Id. (quoting Doe v. Ortho-Clinical Diagnostics, Inc., 440 F. Supp. 2d 465, 471 (M.D.N.C. 2006)). "To complete a differential diagnosis, an expert must then 'rule out' alternative causes, which means opining as to 'specific or individual causation' by 'demonstrating that a

³ Plaintiffs' motion for partial summary judgment remains pending.

given exposure is the cause of a particular individual's disease.'" Id. (citation omitted).

"As a general rule, '*it is not appropriate to rely on a differential diagnosis to prove general causation,*' but establishing general causation is an essential prerequisite to proving specific causation.'"⁴ Id. (emphasis added) (citation omitted).

Even where differential diagnosis opinions are permitted regarding specific causation, such evidence satisfies the Daubert standard only if general causation has already been established. See, e.g., McClain v. Metabolife Int'l, Inc., 401 F.3d 1233, 1253 (11th Cir. 2005) (noting that differential diagnosis satisfies Daubert only if expert can show general toxicity of drug by reliable methods); Norris v. Baxter Healthcare Corp., 397 F.3d 878, 885 (10th Cir. 2005) (holding that plaintiffs' "reliance on differential diagnosis without supporting epidemiological evidence is misplaced"); Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1413 (D. Or. 1996) (holding that differential diagnosis cannot establish general causation because the method "*assumes* that general causation has been proven"). Thus, to allow plaintiffs to rely on differential diagnoses to establish causation would amount to allowing an impermissible end-run around the general causation requirement.

Though the bulk of non-*Fusarium* plaintiffs chose not to file individual responses to defendant's motion, instead choosing to rely on the Plaintiffs' Steering Committee's

⁴ Plaintiffs cite Westberry in support of their argument that a differential diagnosis can be used to show general causation. Their reliance is misplaced because Westberry did not involve a prior Daubert ruling by the court that there was no reliable general causation evidence. In fact, the Westberry court apparently found evidence of general causation, as it noted that the defendant had admitted in its Material Safety Data Sheet that inhalation of talc dust caused sinus irritation. Westberry, 178 F.3d at 264.

global response, some plaintiffs did file responses. The court addresses those responses below.

Plaintiff Gregory Hobbs (07-1188)

Plaintiff Hobbs submitted an individual response to defendant's motion, in which he argued (in total), "As the Court well knows, epidemiological studies, results and conclusions evolve over time. It is possible that a provable link to non-fusarium infections will be established in the future. Accordingly, any dismissal of this action should be without prejudice." Plaintiff Hobbs' speculation about future links between MoistureLoc and non-*Fusarium* infections is not sufficient to survive a motion for summary judgment ripe for ruling today. Moreover, summary judgment is a judgment on the merits, so dismissal without prejudice is not appropriate. See Shoup v. Bell & Howell Co., 872 F.2d 1178, 1181 (4th Cir. 1989).

Plaintiff Enery Fernandez Pinero, et. al. (06-2702)

These Puerto Rico plaintiffs argue that Puerto Rico law does not recognize general causation, that Puerto Rico law does not always require expert testimony to prove causation, and that they have stated a valid failure to warn cause of action. As to the first argument, general causation as a prerequisite to specific causation appears to be a universally accepted concept, and the court has found no Puerto Rico case that holds otherwise. Plaintiffs contend that Puerto Rico v. M/V Emily S., 158 F.R.D. 9 (D.P.R. 1994), stands for the proposition that Puerto Rico courts have rejected the concept of general causation. Their argument misconstrues the holding of the case. The M/V Emily S. court refused to certify the putative class in that case because it rejected the plaintiffs'

argument that causation could be established on a class-wide basis. Id. at 15. As the court noted,

The relevant question, therefore, is not whether Agent Orange has the capacity to cause harm, the generic causation issue, but whether it did cause harm and to whom. That determination is highly individualistic, and depends upon the characteristics of individual plaintiffs (e.g., state of health, lifestyle) and the nature of their exposure to Agent Orange.

Id. (quoting In re Agent Orange Prod. Liab. Litig., 818 F.2d 145, 165 (2d Cir. 1987)).

Thus, while these plaintiffs have submitted affidavits from doctors attesting to the possible link between MoistureLoc and non-*Fusarium* infections, this general causation issue has already been decided in the order rejecting Dr. Cohen's testimony.

Regarding expert testimony, to prove causation Puerto Rico law requires an expert's opinion when "the matter is sufficiently beyond common experience." Collazo-Santiago v. Toyota Motor Corp., 937 F. Supp. 134, 140 (D.P.R. 1996). As the Daubert hearing revealed, this case involves complex medical causation questions involving ophthalmology, microbiology, as well as other scientific specialties that are outside the realm of "common experience." Therefore, expert testimony is required under Puerto Rico law.

Plaintiffs also assert they have stated a valid failure to warn cause of action. However, causation is a required element in every product liability case. As the Supreme Court of Puerto Rico has noted, a strict liability cause of action requires proof of both product defect and causation, and a manufacturer's failure to warn is a type of product defect. Rivera Santana v. Superior Pkg., Inc., 132 D.P.R. 115, 126-28 (P.R. 1992). Thus, plaintiffs' failure to warn claim fails.

Plaintiff Michael Erickson (06-3278)

Plaintiff Erickson alleges he suffered a severe corneal infection caused by *Aspergillus* fungus. Erickson has submitted an affidavit from Dr. William J. Steinbach, M.D., professor of Microbiology at Duke University. Dr. Steinbach concludes that *Fusarium* and *Aspergillus* are so similar that it is highly unlikely that the disinfectant in MoistureLoc would be ineffective against *Fusarium*, yet effective at killing *Aspergillus*. It appears that Erickson's case is the only *Aspergillus* case in this MDL. The court finds that Erickson's case presents a much closer question on whether summary judgment for defendant is appropriate. For this reason, the court will keep defendant's motion for summary judgment as to Erickson's case under advisement.

Plaintiff Sharon Deliz-Velez (07-1568)

Like plaintiff Erickson's case, plaintiff Deliz-Velez's case presents issues which require further consideration by the court. According to a declaration from Dr. Ana Bartolomei, M.D., plaintiff Deliz-Velez developed a central corneal ulcer, which has resulted in impaired vision. Dr. Bartolomei asserts that plaintiff Deliz-Velez's condition was caused by *Acremonium* fungus, of the same phylum as *Fusarium*. The court finds that Deliz-Velez's case, like Erickson's case, presents a much closer question on whether summary judgment for defendant is appropriate. For this reason, the court will also keep defendant's motion for summary judgment as to Deliz-Velez's case under advisement.

Plaintiffs Rudolph Declet-Flores, et. al. (06-3272) and Eva Garcia, et. al. (06-3273)

These plaintiffs, through attorney John Mudd, requested a continuance of the hearing on defendant's motion to accommodate Mr. Mudd's schedule, as well as a Puerto

Rican religious holiday. Because these plaintiffs expressed a desire to participate in oral argument on this matter, the court holds defendant's motion as to these defendants under advisement. Mr. Mudd should contact the court to either schedule a hearing or withdraw his request for argument.

Plaintiff Joan Shallcross (06-3640)

Plaintiff Shallcross has filed a motion to transfer in advance of remand that raises issues requiring further consideration by the court. Therefore, defendant's motion for summary judgment as to Shallcross remains under advisement.

III. CONCLUSION

For the foregoing reasons, defendant's motion for summary judgment is **GRANTED** in part. As explained in the order, the following cases remain under advisement: 07-1568 (Deliz-Velez), 06-3278 (Erickson), 06-3272 (Declet-Flores), 06-3273 (Garcia), and 06-3640 (Shallcross).

AND IT IS SO ORDERED.

A handwritten signature in black ink, appearing to read 'D. Norton', is written over a horizontal line.

DAVID C. NORTON
CHIEF UNITED STATES DISTRICT JUDGE

February 17, 2010
Charleston, South Carolina